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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/287,632 | 04/07/99 | WATERHOUSE P | 021565-060 |

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| EXAMINER |
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| LACOURCIERE, K |

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1635 | 22 |

DATE MAILED: 11/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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|------------------------------|----------------------------------|-----------------------------------|--|
| Office Action Summary | Application No. 09/287,632 | Applicant(s) WATERHOUSE ET AL. | |
| | Examiner Karen A. Lacourciere | Art Unit 1635 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 13-21, 23, 24 and 27-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 22, 25, 26 and 39-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

WILLIAM N. PHILLIPS
PATENT ANALYST

wp

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The objection to claim 22 and the rejection of claim 22 under 35 U.S.C. 112, second paragraph are withdrawn in response to Applicant's amendments filed 08-24-01.

The rejection of claims 1, 11 and 12 under 35 U.S.C. 112, second paragraph, set forth in the prior Office action, mailed 10-03-00, has been withdrawn in response to Applicant's amendments filed 08-24-01.

The rejection of claims 1- 6, 9-12, 22 and 23 under 35 U.S.C. 102(b) as being anticipated by Agrawal et al. has been withdrawn in view of Applicant's arguments filed 08-24-01.

Election/Restriction

In response to the restriction requirement set forth in the Office action mailed 07-21-00, Applicant elected Group I in Paper No. 12. Applicant has now presented arguments which traverse this restriction, after receipt of an action on the merits (mailed 10-03-00).

Applicant argues that claim 23 should have been grouped with the invention of Group III and has requested that claim 23 be withdrawn from consideration. In response to that request, claim 23 has been withdrawn from consideration by the examiner as being drawn to a non-elected invention.

Applicant argues that claims 25 and 26 should be rejoined with the subject matter of the elected group, due to their dependence on claim 22, which was examined with the elected invention. Claims 25 and 26 will be rejoined in view of Applicant's arguments, however, any new

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rejection which is made against claims 25 and 26 which is the result of Applicant's extensive amendments to claim 22 will be considered final.

Claims 1-42 are pending in the instant case. Claims 13-21 and 23, 24 and 27-38 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Claims 1-12, 22, 25 and 26 are considered in this Office action.

The requirement is still deemed proper and is therefore made FINAL.

A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 22, 25, 26 and 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite due to the recitation "essentially similar to a part of at least 10 consecutive nucleotides" in line 8 and in line 11 of the claim. One skilled in the art would not know what nucleotides are encompassed by this term because it is unclear whether the RNA

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hairpin comprises a sequence essentially similar to 10 or more consecutive nucleotides of the nucleic acid of interest or if it comprises a sequence essentially similar to part of 10 or more consecutive nucleotides of the nucleic acid of interest. It is unclear what number of nucleotides “a part of 10 consecutive nucleotides” is meant to encompass and could, for example, include 1 nucleotide. It is unclear how a hairpin which is “essentially similar” (ie. has 75% identity) with 1 nucleotide of the nucleic acid of interest has any relation to said nucleic acid of interest. Therefore, one skilled in the art would not be able to determine what hairpins, and therefore what methods, are encompassed by this claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 5, 6, 8, 11, 12, 22, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Metzloff et al. (submitted on PTO form 1449, filed 07-06-2000).

Metzloff et al. disclose a method wherein a transgene, *chsA*, has been introduced into petunia plants under control of the 35S promoter from cauliflower mosaic virus. This construct produces an RNA molecule comprising a region of 43 base pairs with 80% homology with the

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chsA coding and 3'-UTR regions. This region is located near the base of a loop connecting the base-paired strands. Expression of this RNA results in cosuppression of endogenous chsA, resulting in a phenotypic color change. Therefore, Metzloff et al. anticipates claims 1-3, 5, 6, 8, 11, 12, 22, 25 and 26.

Response to Arguments

Applicant's arguments filed 03-05-01 have been fully considered but they are not persuasive.

Applicant argues that Metzloff et al. do not anticipate the claimed invention because each of the rejected claims is drawn to methods and compositions wherein the hairpin structure is artificial. Applicant argues that the hairpin structure disclosed by Metzloff et al. does not meet the limitations specified in the definition "artificial". Applicant points to page 22, lines 19-28 wherein the term "artificial" has been defined.

These arguments have not been found to be persuasive because the hairpin disclosed by Metzloff et al. does fall within the definition of "artificial", as defined in the instant specification. The definition provided in the instant specification (see p22, line 18 to page 23, line 2, for example) includes "A hairpin RNA can also be indicated as artificial, if it is not comprised within the RNA molecule it is normally associated with. It is conceivable to use in accordance with the invention a chimeric DNA whose transcription results in a hairpin structure with a naturally occurring nucleotide sequence (which otherwise meets the limits as set forth in this specification)

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provided this hairpin RNA is devoid of the surrounding RNA sequences (not involved in the hairpin structure formation).” (see p 22, line 26 to page 23, line 2). The hairpin disclosed by Metzloff et al. is not comprised within the RNA molecule it is normally associated with, for example, the 43 basepair *chsA* hairpin disclosed by Metzloff et al. is normally comprised within a much larger RNA (see for example figure 5 of Metzloff et al.). The *chsA* hairpin disclosed by Metzloff et al. is devoid of the surrounding RNA sequence of the full length *chsA* RNA, wherein the remaining RNA is not involved with the formation of this 43 basepair hairpin. Therefore, the disclosure of Metzloff et al. meets all the limitations set forth in claims 1-3, 5, 6, 8, 11, 12, 22, 25 and 26.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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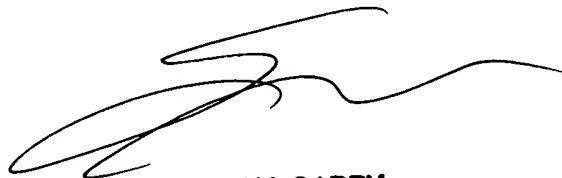
however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Karen A. Lacourciere at telephone number (703)308-7523.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached at (703) 308-0447. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere
November 1, 2001

A handwritten signature in black ink, appearing to read 'SEAN MCGARRY', with a stylized, flowing script.

**SEAN MCGARRY
PRIMARY EXAMINER**